REMARKS/ARGUMENT

An additional dependent claim has been presented for consideration by the Examiner.

Claims 1-5, 12 and 13 have been rejected under 35 U.S.C. § 102 over Tosa and Claims 6, 7 and 14 under 35 U.S.C. § 103 over Tosa in view of Sutherland. Both of these rejections are respectfully traversed.

The present invention relates to a kinetic assay method during the course of which a component of the assay system becomes at least partially bound, directly or indirectly, to the surface of a solid body. It is based on the finding that during the course of such an assay during which such a component becomes so bound, a reliable measurement of said bound or absorbed component, i.e. without interference from the free component in solution, can be obtained by direct and continuous monitoring of the component. The assay of the invention has the advantage that an indication of an unknown ligand concentration can be obtained at a very early stage of the incubation period without the need to wait for some arbitrarily determined endpoint, such as equilibrium. The operator can observe the result continuously and judge whether it is worthwhile taking further readings in an attempt to improve the accuracy of the results. Continuous monitoring allows random errors caused by, for example, problems with instrumentation, to be readily identified.

The independent claim, Claim 1, recites that an analyte dependent parameter associated with the component (e.g., a fluorescent emission) is first measured in a direct and continuous manner, after which the measured parameter is manipulated to quantitatively determine the unknown sample (e.g., analyte concentration), and that the results of the determination are monitored continuously. See, for instance, the continuous monitoring of concentration in application Figure 2. This invention is neither taught nor suggested by the cited references.

The Tosa reference relates to a method and apparatus for an optical immunoassay in which a signal from a labeled antibody is sampled and a time differential value of the signal at the initial stage of a measurement and a signal corresponding to the extent of the immune reaction at a substantially steady point of time or obtained on the basis of the signals so sampled. As described in column 8, the flow chart Figure 2 shows that in step SP1, the start of the measurement is postponed until it is instructed to begin. In step SP2, a signal value

corresponding to a degree of immunity reaction is sampled at predetermined intervals. That value is calculated by subtracting the value obtained at the start of the reaction from the signal obtained at the sampling time. In step SP3, the differential value by time is calculated and in step SP4, a signal value is obtained at a time which is sufficiently long to obtain a value which is nearly saturated. Alternatively, the last signal may be earlier than saturation and at a point deemed sufficient to provide a result. In either procedure, the measured parameter (signal) is manipulated to quantitatively determine the unknown sample (analyte concentration) only once - either after saturation or the earlier time point - and that the result of that single determination noted. It will be appreciated that what the Office Action observes is being "continuously measured" in Tosa (page 2, last paragraph) is the signal and not the results of a manipulative activity carrier out on that signal (as specified in the present claims). Even if Tosa continuously collects data throughout the assay, it is processed only at a point deemed to be the end of the assay, rather than continuously.

Since Tosa does not teach continuous measurement, manipulation of the measured data and continuous monitoring of the manipulated data, a rejection based on Section 102 is respectfully submitted to be inappropriate. Since Tosa also fails to suggest continuous monitoring of manipulated data, it is respectfully submitted that a rejection based on Section 103 would also be inappropriate.

Note also that Tosa requires at least 2 signals to determine concentration, a "differential value" (or rate signal) and a "signal corresponding to the degree of immunity reaction" (i.e., the steady state signal). An advantage of the present invention is that such a pair of signals is not required to determine concentration. Instead concentration can be derived relatively quickly from the kinetic non-steady state data alone.

The Sutherland reference does not overcome the deficiencies in Tosa. Sutherland relates to the use of an optical waveguide for optically ascertained parameters of a species in a liquid analyte. Like Tosa, Sutherland always uses steady state measurements to establish a relationship with those values. It is believed that the Examiner has recognized this, since the Office Action relies on Sutherland for its disclosure of a waveguide and not to suggest a manner in which the use of the Tosa method can, or should, be modified.

In view of these considerations, it is respectfully submitted that the rejections should be withdrawn.

In light of all of the foregoing, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231, on June 19, 2001:

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Respectfully submitted,

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